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10/583,509	06/16/2006	Egisto Boschetti	442187/PALL	3158
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EXAMINER				
HAQ, SHAFIQTUL				
ART UNIT		PAPER NUMBER		
1641				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCpatent@leydig.com
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Office Action Summary

Application No.

10/583,509

Applicant(s)

BOSCHETTI ET AL.

Examiner

SHAFIQU HAQ

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-63 and 99-104 is/are pending in the application.
- 4a) Of the above claim(s) 5,7,9-28,32-51,55,56,58-63,101 and 104 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6,8,29-31,52-54,57,99,100,102 and 103 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/16/06, 7/11/07, 6/29/10 & 6/30/10
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Election-Restriction

1. Applicants' election with traverse, the species of the formula:



a is 3;

 $a', a'',$ and a''' are all 0;

b and b^+ are both 0;

 $c \in \mathbb{Q}_p$

die \mathbb{R}

 θ' is 0;

R_1 and R_2 are H at all occurrences;

(R₄)X is absent;

 \mathbb{R}_4 is \mathbb{H} ;

R₂ is C₆ alkyl:

and the solid support is a cellulose bead. is acknowledged. Claims 1, 3, 4, 6, 8, 29-

31, 52-54, 57, 99, 100, 102 and 103 are generic to the elected species.

Applicants' traversal is on the ground that the claims encompassing the species are linked so as to form a single general inventive concept and there would not be a serious burden on the examiner if the species of the pending claims were searched together because a search for prior art with respect to any of the species would likely uncover references that would be considered by the Examiner during the examination of the other species.

Applicants' arguments have been fully considered but are not found persuasive for the reasons of record as described in the election/restriction requirement mailed 9/29/2010. As described in the election/restriction

requirement mailed 9/29/2010, chromatographic material as defined by the compound of formula I encompasses a large number of structurally, functionally and patentably distinct compounds. The compound of formula I encompasses a large number of structurally and functionally distinct compounds. As for example, in the compound of formula I each of the group R_1 , R_2 , R_4 and R_5 can be independently selected from structurally and functionally distinct group that does not have a common core, as for example, hydroxyl, amide (CONR'R"), alkyl (different chain length), alkaryl (different combinations of alkyl and numerous structures encompassed by "aryl". See the definition of aryl in paragraph [0060], wherein "aryl" refers to cyclic, fused or non-fused and fully aromatic hydrocarbon that has 6 to 12 carbon atoms) and alkoxy (different combinations of oxy and alkyl) are structurally and functionally distinct. The group "het" represents functionally distinct groups that when linked to other groups would provide structurally and functionally distinct linkers/structures. The group R_6 can be selected from structurally and functionally distinct compounds such as sulfonic acid group, phosphoric acid group, carboxyl group, different chain length alkyl, numerous structures encompassed by "aryl" and C_{1-6} -alkaryl (See the definition of aryl in paragraph [0060], wherein "aryl" refers to cyclic, fused or non-fused and fully aromatic hydrocarbon that has 6 to 12 carbon atoms). Similarly, R_3 also represents an enormous number of structurally divergent compounds. These structurally and functionally distinct groups in different combinations would generate an inordinately large number of structurally, functionally and

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patentably distinct compounds encompassed by the compound of formula 1. Therefore, the compounds encompassed by the compound of formula 1 differ materially in chemical functionality and are structurally diverse and dissimilar compounds, which do not possess a substantial common core wherein a reference anticipating one would not necessarily render the other obvious and to search all the above groups in a single application would be an undue burden on the Examiner. Also the fields of search are not coextensive. Additionally, besides performing a class/subclass search, the Examiner performs a commercial data base search and an automated patent system (text) search. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

The examiner searched the prior art and found art anticipating the claims when the search was expanded beyond the elected species (see the following rejection). Therefore, the scope of the claims is restricted to the elected species and thus claims 5, 7, 9-28, 32-51, 55-56, 58-63, 101 and 104 and the remaining subject matter of claims 1, 3-4, 6, 30, 31, 33, 52, 57, 99, 100 and 102 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The withdrawn subject matter of claims 1, 3-4, 6, 30, 31, 33, 52, 57, 99 and 100 is properly restricted as it differs materially in structure and in element from the elected subject matter supra so as to be patentably distinct there from.

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2. Claims 1, 3, 4, 6, 8, 29-31, 52-54, 57, 99, 100, 102 and 103 are examined on merits in this office action.

Objections

3. Claims 1, 3-4, 6, 30, 31, 33, 52, 57, 99, 100 and 102 are objected as being containing non-elected subjected matter. The claims should be amended to exclude non-elected subject matter and within the scope of the elected compounds.

Claim Rejections - 35 USC § 112

4. Claims 1, 3, 4, 6, 8, 29-31, 52-54, 57, 99, 100, 102 and 103 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention." See MPEP § 2163. *Vas-Cath Inc. v. Mahurkar*,

19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. A disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which the invention pertains to make and use the invention as of its filing date. In re Glass, 492 F.2d 1228, 181 USPQ 31 (CCPA 1974). Examples and description should be of sufficient scope as to justify the scope of the claims.

The chromatographic material of formula (I) as claimed encompasses an inordinately a large number of structurally and functionally divergent species of compound and the specification does not provide clear description for a representative number of species linked to a solid support that are capable of binding bovine serum albumin. As for example, the chromatographic material of formula (I) as claimed, can simple be an "hydroxyl" group linked to a solid support. As claimed in claim 1, all of a, b, a', c, d, a", b', a'" and d' can be zero. In that situation, the support represents a support comprising only a hydroxyl group, carboxyl group, sulfonic acid group or a phosphorous acid group (as for example, when R₆ is H, COOH, SO₂OH or PO(OH)₂).

However, the specification does not clearly describe or provide example for a support comprising only a hydroxyl group, carboxyl group, sulfonic acid group or phorsphorous acid group and does not provide clear description for binding characteristics of support having only the above group to bovine albumin at physiological ionic strength. This is a simple example given from

the enormous number of structurally divergent groups encompassed by the chromatographic materials as claimed. However, the various combinations and subcombinations of a, b, a', c, d, a'', b', a''' and d' and various combinations and subcombinations of the structurally and functionally divergent groups encompassed by R₁, R₂, R₃, R₃, R₄, R₅, X and Y would provide an enormous number of structurally and functionally divergent compounds, for which representative species have not been disclosed and clearly described in the specification. A representative species have not been characterized with respect to their binding characteristics for chromatographic column with respect to binding to bovine serum albumin at a physiological ionic strength.

Markush claims must be provided with support in the disclosure for each member of the Markush group. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula. In chemical cases, varying degrees of specificity are required. A disclosure involving a new chemical compound or composition must teach persons skilled in the art how to make the compound or composition. See MPEP § 608.01. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics when coupled

with a known or disclosed structure/function correlation, methods of making the claimed product, or any combination thereof. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. Furthermore, In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement that defines a genus of molecules by only their functional activity does not provide an adequate written description of the genus. The court indicated that although applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules falling within the scope of the claimed genus. Therefore, the disclosure of only a very limited number of compounds from the enormous number of compounds that may be encompassed by the genus as claimed cannot be a representative number of all the unlimited number of structurally divergent and dissimilar compounds as encompassed by the scope of the claims.

A description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. See *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398,1406 (Fed. Cir. 1997). This is analogous to enablement of a genus under section 112, P1, by showing the enablement of

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a representative number of species within the genus. A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not specifically define what constitutes a representative number of species, the courts have indicated what does not constitute the same. See, e.g., *In re Gostelli*, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989), holding that the disclosure of two chemical compounds within a subgenus did not adequately describe such subgenus.

Accordingly, it is deemed that the specification fails to provide adequate written description and clear guidance for all the compounds encompassed by the scope of the chromatographic material of formula (I) as claimed and does not reasonable convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

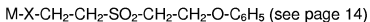
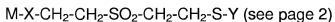
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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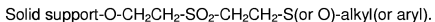
6. Claims 1, 3-4, 29-31, 53-54, 99 and 100 are rejected under 35 U.S.C. 102(b) as being anticipated by Limhe (WO 92/16292).

Limhe teaches chromatographic material (adsorption matrix) having the structures



Wherein M is a matrix (solid support) and **X** can be **oxygen**, nitrogen or sulphur and **Y** can be alkyl or aryl (see lines 30-34 on page 2). Limhe teaches purifying protein from a liquid using the adsorption matrix and possible protein include albumin (page 10, lines 9-25). Limhe teaches ionic strength between 0 and 2.25, which encompasses physiological ionic strength (page 11, lines 29-30 and page 20, lines 5-8).

The above matrix reads on the chromatographic material of formula (I) when in the compound of formula (I) $a=2$ and $R_1, R_2=H$, representing $(CR_1R_2)_a$ as CH_2CH_2 ; $b=1$, $het=SO_2$, representing $(het)_b$ as SO_2 ; $a'=2$ and $R_1, R_2=H$, representing $(CR_1R_2)_{a'}$ as CH_2CH_2 ; $b'=1$, $het=S$ or O , representing $(het)_{b'}$ as S or O ; R_6 = alkyl or aryl; and all of c , d , a'' , a''' and d' are zero. With the above selection, the compounds that can be represented is shown below:



With regard to claims 3, and 4, as described above a and a' are 2.

With regard to claims 29-31, as described above d' is zero and R_6 is alkyl or aryl.

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With regard to claims 99 and 100, as described above $R_1, R_2 = H$ and R_6 is alkyl, as for example C_2 -alkyl (page 3, lines 10-11).

With regard to claims 53 and 54, Lihme teaches adsorption matrix comprising organic material such as agarose (col. 3, lines 4-6).

Therefore, the reference is deemed to anticipate the cited claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 6, 8 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Limhe (WO 92/16292) as described above and further in view of Gemeiner *et al* (Journal of Chromatography B 1998).

See the above teaching of Lihme for cellulose matrix having a chemical group as chromatographic support for adsorption of proteins.

With regard to claim 57, above reference teach cellulose matrix but do to teach the cellulose as beads form for use as adsorption chromatography.

Gemeiner *et al* teach affinity sorbents based on cellulose materials as a support (see abstract). Gemeiner *et al* teach cellulose in beads form has the largest diameter of all supports tested (page 254, 2nd paragraph, right col.) and they offer low non-specific adsorption, outstanding physical strength and

high pressure resistance capabilities (page 257, 2nd paragraph, left col.) and teach cellulose beads as an affinity matrix (page 259, line 3 on left col.).

Therefore, given the fact that cellulose in beads for is common in the field of chromatography and is advantageous for its non-specific adsorption and outstanding physical strength and high pressure resistance capabilities, it would be obvious to one of ordinary skill in the art at the time the invention was made to substitute the matrix of Limhe with the cellulose bead matrix with the expectation of providing a similar chromatographic support for adsorption of proteins with a reasonable expectation of success.

With regard to claims 6 and 8, as described in the above 102 (b) rejection, a and a' are disclosed as 2. Therefore, the compounds are homologs and wherein the difference lies in number of repeating unit (in this case, by one repeat unit). However, homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH₂- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

Conclusion

9. No claims are allowed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shafiqul Haq/
Primary Examiner, Art Unit 1641